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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,568	01/18/2001	Yoji Ikawa	Q61014	5597

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/670,568

Applicant(s)

IKAWA ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 7, 16, 17 and 19-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 24 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 7, 16, 17, 19-23 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: a copy of 1449, previously considered IDS filed on 01/18/01.

DETAILED ACTION

Applicant's amendment filed on 12/31/2003 is acknowledged. Claims 1-3, 6, 7, and 20-22 are amended, and claims 23-29 are new.

Claims 1-3, 6, 7, 16, 17, and 19-29 are pending and under consideration.

This Office action contains new grounds of rejections.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

Receipt of the substitute declaration filed on 12/31/2003 is acknowledged, and the substitute declaration is accepted.

Sequence Rules

Receipt of the new sequence listing, and the statement that CRF, and the paper copy of the sequence listing are the same filed on 12/31/2003 is acknowledged. A new CRF appears to be filed at the same time. However, the CRF in floppy disk is not in the application. It is regretted that the Office could not locate the disk at this time.

Applicant is kindly requested to provide the Office the copy of (1) sequence listing, (2) the statement that CRF, and the paper copy of the sequence listing are the same filed, and (3) CRF filed on 12/31/2003.

Information Disclosure Statement

The IDS submitted on 01/18/2001 was considered on 06/24/2003. A copy of the corresponding 1449, printed out from the IFW is attached with this Office action.

Claim Rejections - 35 USC § 112, Withdrawn

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Claims 2, 3, 6, 7, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 6, and 7 recites "under stringent conditions" but it is not clear what the metes and bounds.

Claim Rejections - 35 USC § 102

Claims **2, 6, 7, and 19 remain rejected**, and the **new claims 23, 27, and 28 are also rejected** under 35 U.S.C. 102(b) as being anticipated by GenEmbl accession number Y114146 (Sep. 02, 1997) as evidenced by Kaghad et al (IDS, Cell vol. 90, pages 809-19).

Claims 2, 6, 7, and 19 are interpreted as drawn to an isolated DNA molecule that hybridizes to the protein coding region of SEQ ID NO:2 under the recited condition wherein said DNA encodes a protein with any one of transcriptional, growth inhibition, or apoptosis induction activity in claim 2. The new claims 23, and 27, and 28 are broadly interpreted drawn to an isolated DAN molecule encoding a polypeptide with an undefined number of amino acids changes either from SEQ ID NO:1 or the specified portion of SEQ ID NO:1, based on the proviso language of "one **or a few** amino acids", wherein the claimed polypeptide has any one of transcriptional, growth inhibition, or apoptosis induction activity.

Applicant argues the amended claims 1, 20, 21 recite additional structural features not taught by the art. This argument is persuasive, therefore, the rejection of claim 1, 20, and 21 is withdrawn because the amended claims are no longer anticipated

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by the art. However, all other previously rejected claims 2, 6, 7, and 19 remain rejected and new claims 23, 27, and 28 are also rejected. Applicant does not argue about the rejection of claims 2, 6, 7, and 19.

The amended claims 2, 6, 7, and 19 still read on the prior art because the protein coding region of Y114146 has about 70 % sequence homology to the protein coding region of instant SEQ ID NO:2. It is the Office's position that 70 % sequence homology of more than 1 kb DNA would hybridizes under the specified conditions. Whether the prior art does not meet the limitations of the claims 2, 6, 7, and 19 require experiments involving DNA hybridization. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the DNA of the prior art does not hybridizes under the specific hybridization. In the absence of evidence to the contrary, the burden is on the applicant to prove that the DNA of the prior art does not hybridizes. This rejection would be obviated by presenting the Office with the scientific data showing that the protein coding region of Y114146 does not hybridizes SEQ ID NO:2 or the protein coding region of SEQ ID NO:2.

As for the new claims 23, 27, 28, the specification does not define the maximum number of amino acids that has to be added, deleted, or substituted in order to meet the limitation "**a few** amino acids", which is subjected to many different interpretations. Note the rejection under 35 U.S.C. 112, second paragraph below. As the previously provided sequence alignment of the coding region of Y114146 against the instant SEQ ID NO:1 indicates, Y114146 encodes a protein that has about 72 % sequence identity to instant SEQ ID NO:1. As for the functional limitations in the claims, GenEmbl accession

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number Y11414 teaches a nucleic acid encoding p73beta protein (Kaghad et al teach at page 819 last sentence that the DNA encoding p73beta protein is deposited in EMBL data base with the accession number Y11414). Kaghad et al teach at page 813, right column that the p73beta protein has transcriptional activity and growth suppression activity.

The rejection of claims 1, 16, 17, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Chan et al (1993, Proc. Natl. Acad. Sci. USA. vol. 90, pages 11371-5) is **withdrawn** because the amended claims are no longer anticipated by the art.

The Following Are New Grounds of Rejections

Claim Rejections - 35 USC § 112

Claims 21, and 23, 25-29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "the DNA binding domain" in 6. There is insufficient antecedent basis for this limitation in the claim.

Claims 23, 27, and 28 recite "a few amino acids" to indicate the number of amino acids being mutated from SEQ ID NO:1, but it is not clear what the metes and bounds are. It is the Office's position the phrase is too vague to draw a property line, which might lead to confusion to determine whether someone is infringing on the patent if issued. The dependent claims 25, 26, and 29 are also rejected for the same reasons.

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Claims 1, 16, 17, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with **the written description requirement**. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

This new matter rejection is made because the specification as originally filed does not reasonably communicate that applicant's invention is an isolated DNA molecule that encodes a polypeptide with at least 50% homology to the entire SEQ ID NO:1, at least 45 % homology to the transcription activation domain, 90% homology to DNA binding domain, **and** at least 80% homology to oligomerization domain. Applicant states that the support is found at pages 27-28. However, the specification as originally filed has support for encodes a polypeptide with at least 50% homology to the entire SEQ ID NO:1, at least 45 % homology to the transcription activation domain, 90% homology to DNA binding domain, **or** at least 80% homology to oligomerization domain. The scope in the specification as originally filed and the scope in the amended base claim 1 is different, thus it is new matter.

Allowable Subject Matter

Claims 3, and 24 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER